DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Philips Medical Systems Nederland B.V.
% Ms. Liselotte Kornmann
Regulatory Affairs Manager
Veenpluis 4-6
Best, 5684 PC
THE NETHERLANDS

January 30, 2015

Re: K142273
Trade/Device Name: EmboGuide
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, LLZ, JAK
Dated: December 16, 2014
Received: January 12, 2015

Dear Ms. Kornmann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert A Ochs

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K142273

Device Name

EmboGuide

Indications for Use *(Describe)*

EmboGuide is a post processing software medical device intended to assist physicians in performing embolization of hypervascular tumors in the liver using interventional X-ray. It provides tools to help the user with the analysis of 3D rotational angiography images. Its output is intended as an adjunct means to help with the planning and guidance of the embolization procedure. It provides real time overlay of 3D rotational angiography images on live 2D X-ray images of the same anatomy to support device/catheter guidance.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is prepared in accordance with 21 CFR §807.92.

Date Prepared:	December 16, 2014	
Manufacturer:	Philips Medical Systems Nederland B.V. Veenpluis 4-6 5684 PC Best The Netherlands Establishment Registration Number: 3003768277	
Contact Person:	Mr. Hans Venings Director of Regulatory Affairs Phone: +31 611348827 E-mail: hans.venings@philips.com	
Device:	Trade Name:	**EmboGuide**
	Device Name:	**EmboGuide Rel. 1.0**
	Classification Name:	Image-intensified fluoroscopic x-ray system
	Classification Regulation:	21CFR §892.1650
	Classification Panel:	Radiology
	Device Class:	Class II
	Primary Product Code: Secondary Product Code:	OWB (Interventional x-ray system) LLZ (system, image processing, radiological), JAK (system, x-ray, tomography, computed)
Primary Predicate Device:	Trade Name:	3D Roadmap Rel. 1
	Manufacturer:	Philips Medical Systems Nederland B.V.
	510(k) Clearance:	K121772 (March 21, 2013)
	Classification Regulation:	21 CFR, Part 892.1650
	Classification Name:	Image-intensified fluoroscopic x-ray system
	Classification Panel:	Radiology
	Device Class:	Class II
	Primary Product Code: Secondary Product Code:	OWB (Interventional x-ray system) LLZ (system, image processing, radiological), JAK (system, x-ray, tomography, computed)

Reference Device:	Trade Name:	FlightPlan for Liver
	Manufacturer:	GE Healthcare
	510(k) Clearance:	K121200 (November 2, 2012)
	Classification Regulation:	21 CFR, Part 892.2050
	Classification Name:	Picture Archiving and Communications System
	Classification Panel:	Radiology
	Device Class:	Class II
	Product Code:	LLZ

Device description:

EmboGuide is a post processing software medical device intended to assist physicians in performing embolization of hypervascular tumors in the liver using interventional X-ray. **EmboGuide** is an extension of XperCT and intended to be used in combination with an Allura interventional X-ray system. Like the primary predicate device *3D Roadmap*, **EmboGuide** adds specific functionality to the Allura system but does not change the overall intended use of the Allura system or the overall risk profile.

EmboGuide uses a 3D volume reconstructed from 3D rotational angiography images acquired on the Allura X-ray system and the segmentation of lesions on previously acquired CT, MR or XperCT datasets as input data for the planning of the embolization. The physician can use this input data to analyze the vasculature of lesions, and to identify and annotate the blood vessels that shall be embolized (feeding vessels). The real-time overlay and registration of the 3D volume on live 2D X-ray images from the Allura X-ray system of the same anatomy can be used as additional 3D image guidance to support the navigation of the device/catheter. Planning data, like the earlier annotated feeding vessels and/or 3D landmarks can be displayed on 2D-3D fused images as supporting information.

Indications for Use:

EmboGuide *is a post processing software medical device intended to assist physicians in performing embolization of hypervascular tumors in the liver using interventional X-ray. It provides tools to help the user with the analysis of 3D rotational angiography images. Its output is intended as an adjunct means to help with the planning and guidance of the embolization procedure. It provides real time overlay of 3D rotational angiography images on live 2D X-ray images of the same anatomy to support device/catheter guidance.*

EmboGuide has similar indications for use as its primary predicate device *3D Roadmap*:

- Similar to *3D Roadmap*, **EmboGuide** is a supportive tool to help the physician with performing an interventional procedure on the Allura X-ray Xper system.
- Similar to *3D Roadmap*, **EmboGuide** provides the real time overlay of 3D rotational angiography images on live 2D X-ray images of the same anatomy to support device/catheter guidance.

Technological characteristics:

EmboGuide employs the same fundamental scientific technology as its primary predicate device *3D Roadmap*.

- Both **EmboGuide** and *3D Roadmap* are extensions of the Allura interventional X-ray system (K133292).
- Both **EmboGuide** and *3D Roadmap* use 3D volumes reconstructed from 3D rotational angiography images as input.
- Both **EmboGuide** and *3D Roadmap* provide the overlay of 3D volume on live fluoroscopic images acquired from the Allura X-ray system.
- Both **EmboGuide** and *3D Roadmap* provide dynamic update to changes of the position of the X-ray equipment; the 3D volume is automatically adjusted to any gantry changes and any lateral or longitudinal table movements.
- **EmboGuide** provides additional functionality to assist the clinical user with identifying arteries that are feeding into hypervascular tumors and to plan for the embolization treatment of these tumors. This is functionality to further support the clinician in performing interventions and does not raise new questions related to safety and effectiveness. Furthermore, the scientific method is comparable to reference device *FlightPlan for Liver* which also implements an algorithm for detecting vessels leading to a lesion.

Summary of Non-clinical Performance Data:

Non-clinical performance testing has been performed on **EmboGuide** and demonstrates compliance with the following International and FDA-recognized consensus standards and FDA guidance document:

- IEC 62304 Medical device software – Software life cycle processes (Ed. 1.0, 2006),
- IEC 62366 Medical devices – Application of usability engineering to medical devices (Ed. 1.0, 2007),
- ISO 14971 Medical devices – Application of risk management to medical devices (Ed. 2.0, 2007),
- NEMA PS 3.1-3.20 Digital Imaging and Communications in Medicine (DICOM) Set (2011), and
- Guidance for Industry and FDA Staff – Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (issued May 11, 2005, document number 337).

Verification and validation tests have been performed to address intended use, the technical claims, requirement specifications and the risk management results. The test results in this 510(k) premarket notification demonstrate that **EmboGuide**:

- complies with the aforementioned international and FDA-recognized consensus standards and FDA guidance document, and
- meets the acceptance criteria and is adequate for its intended use.

Summary of Clinical Performance Data:

Clinical testing of **EmboGuide** included an initial reading study to validate the user interaction in the embolization planning workstep and a clinical validation study to validate the correctness and consistency of **EmboGuide** to identify feeding vessels leading to previously segmented lesions. Substantial equivalence was based in part on the clinical validation study of the **EmboGuide** software.

Clinical Validation Study

The clinical validation study of **EmboGuide** was based on a retrospective image collection of 63 patients (outside the United States) and included a prospective review of randomized images; 44 subjects were included in the study and 19 were excluded. First, feeding vessels of the lesions were defined by consensus of two experienced interventional radiologists (located outside the United States) who also performed the procedures by using all available information (2D angiography, MR and /or CT, Cone Beam CT (CBCT) and EmboGuide). This was used as the "ground truth". Another three independent interventional radiologists (located out- and inside the United States) determined the feeding vessels based on CBCT, **EmboGuide** automatic feeder detection (AFD) and by subsequent review i.e., adding and deleting feeding vessels. Finally, the "ground truth" was compared with the determination of feeding vessels by the three independent readers for CBCT, **EmboGuide** AFD alone, and **EmboGuide** used in normal clinical practice (i.e., adding or removing vessels). The performance of **EmboGuide** was evaluated by the sensitivity. The study also evaluated whether consistent results could be obtained across multiple users. The study showed that:

- the sensitivity of **EmboGuide** in clinical routine use for identification of tumor feeding vessels is 83+/- 8% with a CI of 95% for HCC patients with diagnostic quality CBCT images and no tumors or feeding vessels outside the volume imaged with CBCT.
- **EmboGuide** as it will be used in normal clinical practice provides for a higher sensitivity to identify feeding vessels compared to CBCT,
- **EmboGuide** AFD alone provides for a higher sensitivity to identify feeding vessels compared to CBCT,
- the overall agreement among readers for identification of feeding vessels using both the **EmboGuide** AFD and **EmboGuide** as it will be used in clinical practice was greater than the pre-selected acceptance criteria of 0.7 (i.e., 70%) indicating that for both approaches results in a consistent identification of feeding vessels for different readers,
- the agreement among readers for identification of feeding vessels using the **EmboGuide** AFD alone was close to one (i.e., 0.99 with the lower bound of the 95% CI of 0.986), and
- the overall agreement among readers for identification of feeding vessels using the CBCT (i.e., 0.69 with lower 95%CI of 0.648) was less than the pre-selected acceptance criteria of 0.7 (i.e., 70%) indicating that identification of feeding vessels using this method may not be consistent for different readers.

The clinical performance data as documented in the clinical validation study demonstrate that **EmboGuide** performs comparably to the reference device *FlightPlan for Liver* that is currently marketed.

Substantial Equivalence Conclusion:	Based on the information and comparison presented in the aforementioned sections, the proposed **EmboGuide Rel. 1.0** software medical device is considered substantially equivalent to the currently marketed predicate device: *3D Roadmap*, in terms of design features, fundamental scientific technology, indications for use, and safety and effectiveness. For specific functionality to assist the clinical user in analyzing the 3D images of the vascular tree to plan for the embolization treatment, **EmboGuide Rel. 1.0** is comparable to the currently marketed reference device *FlightPlan for Liver*. The (non-)clinical performance tests provided in this 510(k) premarket notification demonstrates that the proposed **EmboGuide Rel. 1.0** is as safe and effective as its predicate device without raising any new safety and/or effectiveness concerns